(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) EP 1 093 767 A1

(12) EUROPEAN PATENT APPLICATION

(43) Date of publication:
25.04.2001 Bulletin 2001/17

(51) Int Cl.[7]: **A61C 8/00**, A61B 10/00

(21) Application number: **99308320.3**

(22) Date of filing: **21.10.1999**

(84) Designated Contracting States:
AT BE CH CY DE DK ES FI FR GB GR IE IT LI LU MC NL PT SE
Designated Extension States:
AL LT LV MK RO SI

(71) Applicant: **Ashman, Arthur**
Westport, CT 06880 (US)

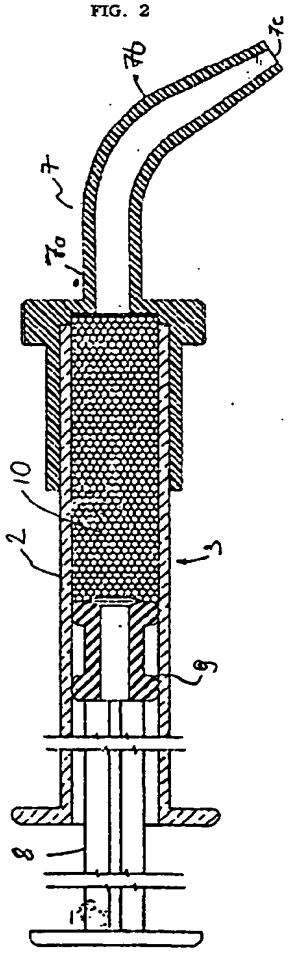
(72) Inventor: **Ashman, Arthur**
Westport, CT 06880 (US)

(74) Representative: **Marchant, James Ian et al**
Elkington and Fife,
Prospect House,
8 Pembroke Road
Sevenoaks, Kent TN13 1XR (GB)

(54) Combination syringe and aspirator for bone regeneration material and method for using the improved syringe

(57) An improved assembly of a syringe and a nozzle tip for aspirating marrow blood from a surgical site and a method for using this improved syringe. The syringe includes a nozzle tip of special construction which has a sleeve portion, which fits on the free end of the barrel of the syringe, and a curved aspirating nozzle end. The nozzle tip includes a filter screen of preselected mesh size. A sufficient amount of marrow blood is aspirated through the curved aspirating nozzle end and the filter screen of the nozzle tip, thereby moving a preselected amount of marrow blood into the barrel of the syringe. The aspirated marrow blood then mixes with the granules of bone regeneration material disposed in the barrel of the syringe to form a viscous fluid mixture therein. The excess marrow blood, if any, is expelled through the curved aspirating nozzle end by applying a moderate manual pressure to the plunger of the syringe. After visual inspection of the formed viscous fluid mixture in the syringe, the nozzle tip is then manually removed from the syringe and the viscous fluid mixture is applied to a surgical site by applying manually pressure on the plunger of the syringe. The filter screen is mounted inside a flange adjoining the sleeve portion in the nozzle tip. This filter screen has openings of predetermined mesh size to prevent the granules of bone regeneration material from exiting through the nozzle tip during the aspirating of the marrow blood into the syringe barrel and prior to the removal of the nozzle from the syringe barrel and the expelling of the viscous mixture to a surgical site.

FIG. 2



EP 1 093 767 A1

Description

[0001] The invention relates to a nozzle tip of special construction mounted on the barrel of a standard syringe for dispensing bone regeneration materials to a surgical site. The nozzle tip and syringe are used to aspirate marrow blood from a surgical site; then mixing the collected blood marrow with granular bone regeneration material stored in the barrel of the syringe to form a viscous fluid mixture therein; then manually removing the nozzle tip from the syringe barrel; and then dispensing the viscous fluid mixture to the surgical site by manual application of pressure on the plunger of the syringe. Bone regeneration materials are known in the art For example, hardtissue implant materials are known, such as the calcified microporous co-polymer material marketed under the trademarks Bioplant® HTR® *Synthetic Bone™* alloplast. The aforesaid bone regeneration material has been widely accepted in medicine, dentistry and veterinary medicine as a prostethic bone material to repair injured or diseased bone. The following co-invented U.S. patents describe the use of such bone generation materials: 4,199,864; 4,244,689; 4,535,485; 4,536,158; 4,547,327; 4,547,390 and 4,728,570. The aforelisted co-invented U.S. patents are incorporated by reference herein. For many applications of said Bioplant®. HTR® material the application of this material in granular form has proven to have many advantages. For example, granular Bioplant®, HTR® material has proven particularly useful in a tooth extraction procedure. A simple injection of granular Bioplant®, HTR® material into the tooth socket, following immediately after extraction of the tooth, either significantly reduces or completely prevents the usual 40% to 60% percent bone loss that otherwise occurs within 2-3 years after tooth extraction, and eliminates much of the pain and inflammation of the tooth socket (post-extraction alveolar osteitis). Granular Bioplant®, HTR®material works best when it is thoroughly wetted with marrow blood before being applied to a surgical site.

SUMMARY OF THE INVENTION

[0002] It is an object of the present invention to provide a side improved syringe and nozzle tip construction for producing and then dispensing a viscous mixture of granular Bioplant®, HTR® material and marrow blood, obtained from a surgical site.

[0003] It is another object of the invention to provide a simple method of mixing aspirated marrow blood from a surgical site with granular bone regneration material inside the barrel of a syringe and, by the use of an improved nozzle tip construction, mounted on a standard syringe, prevent excessive loss of marrow blood and/or granular bone regeneration material during the mixing operation.

[0004] It is another object of this invention to provide an aseptic method for mixing aspirated marrow blood from a surgical site with granular bone regeneration material and then applying, in an aseptic manner, the Viscous mixture obtained by the mixing in the sterile syringe barrel to the surgical site.

[0005] Low density polyethylene has been found to be particularly advantageous for manufacturing the entire nozzle tip construction including the filter screen which is mounted inside the nozzle tip. The openings of the mesh screen must be smaller than the grain size of the granular bone regeneration material inside the syringe barrel. A mesh opening size of about 105 microns has been found to work best with the method of the invention because it can be used with several standard granular sizes of Bioplant®, HTR® materials.

[0006] Further details regarding the nozzle tip construction, and the method of forming a viscous mixture of granular Bioplant® HTR® polymer material and then applying it to a surgical site will be provided in the following description of preferred embodiments in conjunction with the accompanying drawings.

BRIEF DESCRIPITON OF THE DRAWINGS

[0007]

Figure 1 is a cross-sectional view of the nozzle tip of the invention;

Figure 2 is a cross-sectionlal view of a standard straight barrel syringe holding bone regeneration material, with a nozzle tip of the invention, mounted thereon, which, standard type of syringe is commonly used in applying bone regeneration, materials to a surgical site;

Figure 3 is a cross-sectional view of the straight barrel syringe of Figure 2 with the nozzle tip of Figure 2 mounted thereon during the step of aspirating marrow blood from a tooth socket and mixing it with bone regeneration material in the syringe;

Figure 4 is a cross-sectional view of the straight barrel syringe of Figure 2 after the mixing step has been completed and the nozzle tip has been manually removed so that the viscous mass formed by the mixture of marrow blood and bone regeneration material is ready to be applied to a surgical site;

Figure 5 is a view in perspective showing the step of aspirating marrow blood from a tooth socket with the nozzle tip construction of the invention; and

Figure 6 is a view in perspective showing the step of applying the viscous mixture in the syringe barrel to the tooth socket.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0008] Although the principles of this invention are applicable to other surgical procedures than a tooth extraction, the invention, will be fully understood from an explanation of its application to a preferred embodiment of

a syringe and special nozzle tip construction as illustrated in Figures 1-6.

[0009] Shown in FIG. 1 is a cross-sectional view of the nozzle tip 1 of this invention. The nozzle tip 1 includes a sleeve portion 1a which has an internal diameter which corresponds to the external diameter of the barrel 2 of the syringe 3 illustrated in FIG. 2. The nozzle tip 1 is therefore mounted on the syringe barrel 2 by means of a friction fit. The syringe 3 is. of the type that is commonly used for dispensing granular bone regeneration material, such as Bioplant®, HTR® material. The nozzle tip has a flange 4 which has a recess 5. A screen 6 having a mesh size of about 105 microns is mounted inside the recess 5. The nozzle tip further has a neck portion 7 with a passage 7d extending therethrough. The neck portion 7 includes an axially straight portion 7a extending from the flange 4 and integral therewith, and a curved portion 7b through the opening 7c thereof the marrow blood can aspirated. The neck portion 7 is integral with the flange 4 and the entire nozzle tip construction including the neck portion 7 and so 6 are preferably made by a known, molding operation of low density polyethylene.

[0010] FIG. 2 illustrates in cross-section a syringe 3 with the nozzle tip 1 mounted thereon. The barrel 2 of the syringe 3 is filled with a granular bone generation material 10, such as Bioplant®, HTR® material. This barrel is made of either glass or transparent plastic material. The syringe 3 further has the standard, plunger 8 on the front and of which is mounted a piston 9. By applying manual pressure to the plunger 8 the piston 9 can be reciprocally slidably axially moved inside the barrel 2 of the syringe 3. The entire assembly, as illustrated in Figure 2, is mounted inside a non-illustrated conventional blister pack, in which it is distributed to the dentist, surgeon or veterinary practitioner for application of the bone regeneration material to a surgical site. This entire assembly is intended for a single use only and the assembly and blister pack is intended to be discarded after this single use.

[0011] FIGS. 3 and 5 illustrate the aspirating step of the invention using the nozzle tip 1 and syringe 3 of the invention. The curved portion 7b of the nozzle tip 1 is inserted, by way of example, by the dentist into the tooth socket IIa of a jaw bone 11b of a patient immediately after a non-illustrated tooth has been extracted from the tooth socket 11a. Marrow blood 11 is then aspirated through the opening 7c of the neck portion 7 by manually retracting the plunger 8. The aspirated marrow blood 11 flows through neck portion 7 and the screen 6 into the barrel 2 of the syringe where it immediately begins to soak the bone regeneration material 10 with marrow blood 11. By visually examining the syringe 3 the dentist or surgeon determines when a sufficient marrow blood 11 has been aspirated from the tooth socket 11a and has mixed with the bone regeneration material 10. If an insufficient amount of marrow blood has been aspirated the afore-described steps are repeated. If excess marrow blood has been aspirated this excess marrow blood is expelled by slightly manually moving the plunger forward. While these steps are carried out the screen 6 prevents the clogging with granular bone regeneration material of the passage 7d in the straight neck portion 7a of the neck portion 7.

[0012] By visually examining the mixture of marrow blood and bone regeneration material inside the syringe barrel 2, the dentist can determine when the mixture 10a of bone regeneration material and marrow blood 11 contains a sufficient amount of marrow blood and thereby the mixture has became sufficiently viscous to be applied to a surgical site. The nozzle tip 1 is then manually slid off the syringe barrel 2 as is shown in FIG. 4.

[0013] As is shown in FIG. 6 the viscous mixture 10a is then applied to a surgical site, such as a tooth socket 11a, by applying manual pressure to the plunger 8. Once this step has been completed the surgeon may apply sutures to the surgical site if the surgical condition of the patient warrants such a step.

[0014] Although the nozzle tip construction and method of applying a viscous mass of a mixture of marrow blood and bone regeneration material of the present invention have been described in terms of the presently preferred embodiments, it is to be understood that such disclosure is not to be interpreted as limiting. For example, it should be noted that the syringe assembly and method of the invention can be used in other surgical procedures than tooth extraction and can find application in surgery and veterinary medicine. Accordingly, it is intended that the appended claims be interpreted as covering all alterations and modifications as fall within the true spirit and scope of the invention.

Claims

1. A syringe and nozzle tip assembly for applying a viscous mixture of marrow blood and bone regeneration material to a surgical site, comprising in combination,

   a) a syringe having a syringe barrel which has a front end and a rear end, said syringe barrel being made of either glass or plastic transparent material and containing a predetermined amount of granular bone regeneration material ;

   b) a piston slidably reciprocally movably mounted in said syringe barrel;

   c) a plunger being connected at its front end to said piston and axially extending rearwardly from said syringe barrel through said rear end thereof; and

   d) a nozzle tip having a flange and a sleeve portion which is coaxially mounted on the front end of said syringe barrel by means of a friction fit; said nozzle tip having a curved neck portion

with a passage extending there through for aspirating marrow blood from a surgical site and transporting it into said syringe barrel.

2. The syringe and nozzle tip assembly as set forth in claim 1, wherein said nozzle tip includes a flange and a recess disposed therein, a screen mounted in said recess of said flange for preventing the discharge of granular bone regeneration material disposed in said syringe barrel during the step of aspirating the marrow blood.

3. The syringe and nozzle tip assembly as set forth in claim 2, wherein said screen and curved neck portion are integral with said nozzle tip and said nozzle tip and screen are made of low density

4. The syringe and nozzle tip assembly as set forth in claim 3, wherein the openings of said screen have a mesh size of about 105 microns.

5. A method of applying a viscous mixture of marrow blood and bone marrow regeneration material to a surgical site, comprising the steps of

a) aspirating a sufficient amount of marrow blood from a surgical site through a nozzle tip and into the transparent barrel of a syringe in which there is disposed a predetermined amount of granular bone regeneration material, said aspirating step is effected by moving rearwardly the plunger of a piston slidably movably in said syringe to thereby cause a predetermined amount of marrow blood to flow through the passage of a curved neck portion of said nozzle tip into said syringe barrel;
b) mixing said aspirated marrow blood with said bone regeneration material in said syringe barrel until a sufficient amount of viscous mass of a mixture of bone regeneration material and marrow blood has formed in said syringe barrel;
c) slidably removing the nozzle tip which is mounted on the front end
of said syringe barrel; and
d) applying said viscous mixture of marrow blood and bone regeneration material to a surgical site by axially advancing the plunger of said piston thereby expelling a predetermined amount of said viscous mass from the front end of said syringe barrel.

6. The method of applying a viscous mixture of marrow blood and bone marrow regeneration material to a surgical site, as set forth in claim 5, including the additional step of expelling any excess marrow blood in said syringe barrel through said nozzle tip prior to slidably removing said nozzle tip from said syringe barrel.

7. The method of applying a viscous mixture of marrow blood and bone regeneration material to a surgical site, as set forth in claim 6, wherein said bone regenerating material is Bioplant®, HTR® material.

FIG. 1

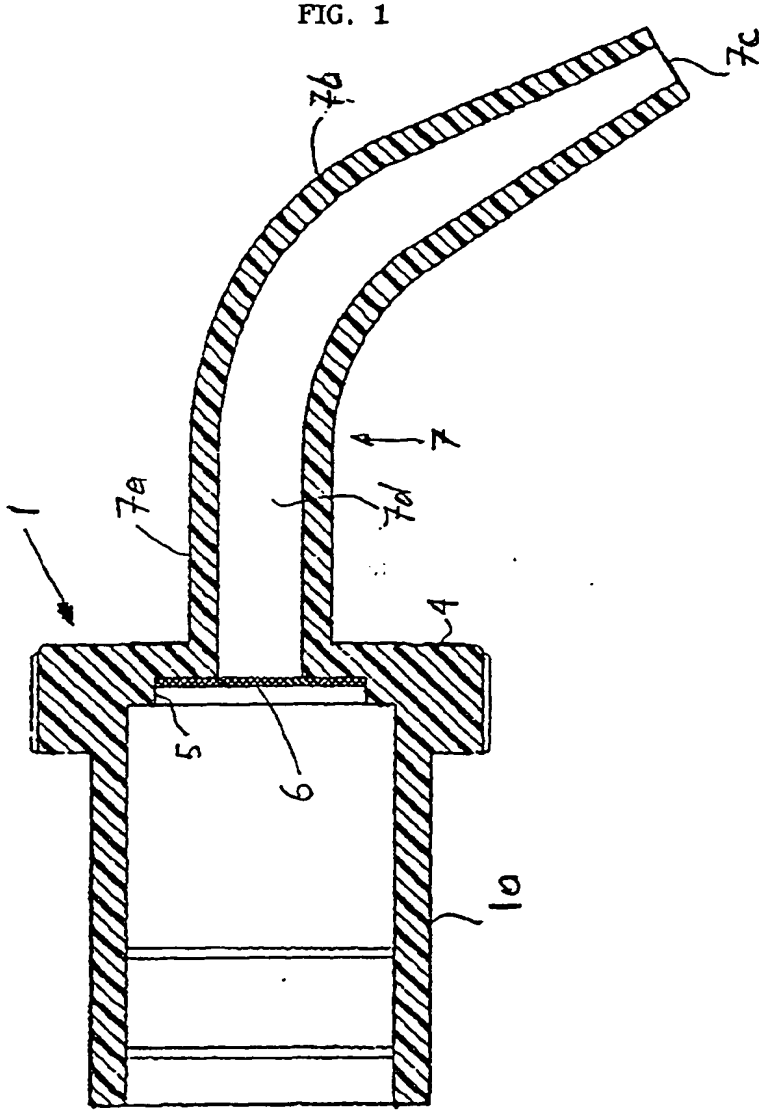


FIG. 2

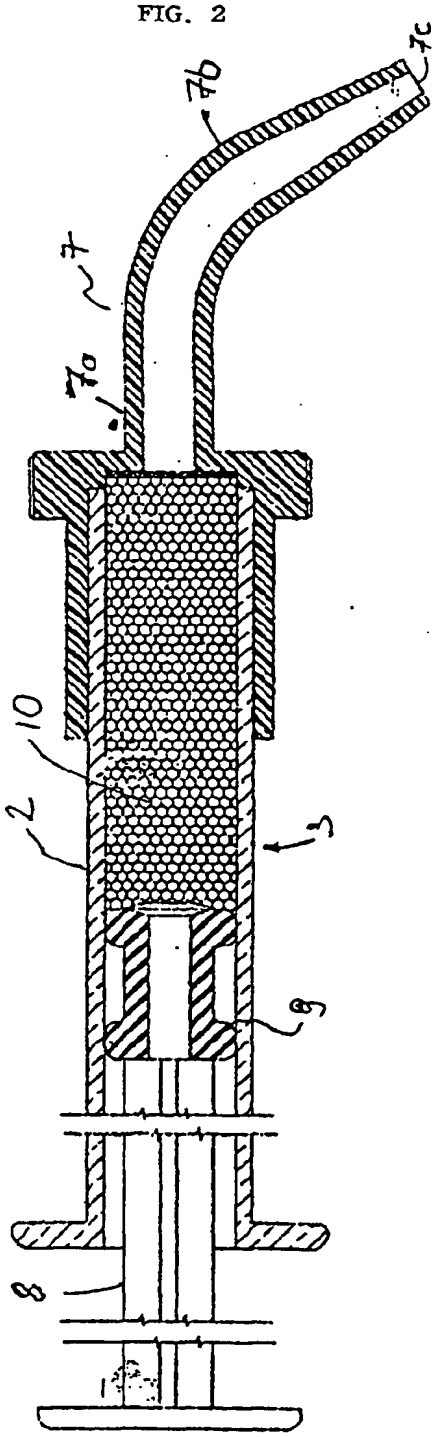


FIG. 3

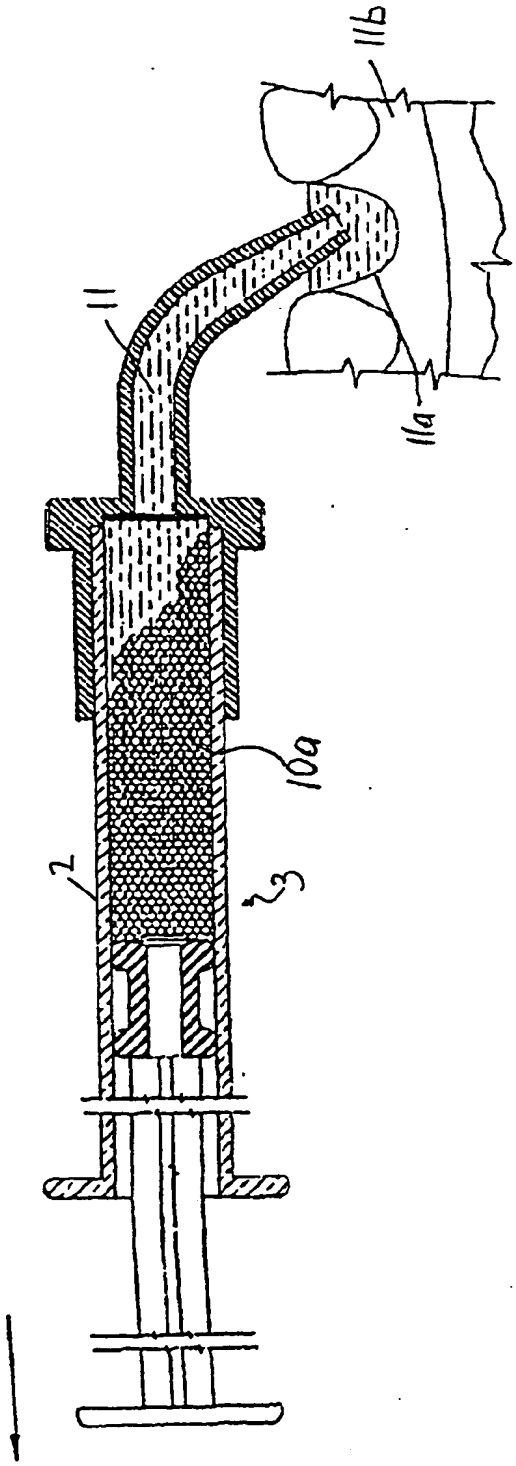


FIG. 4

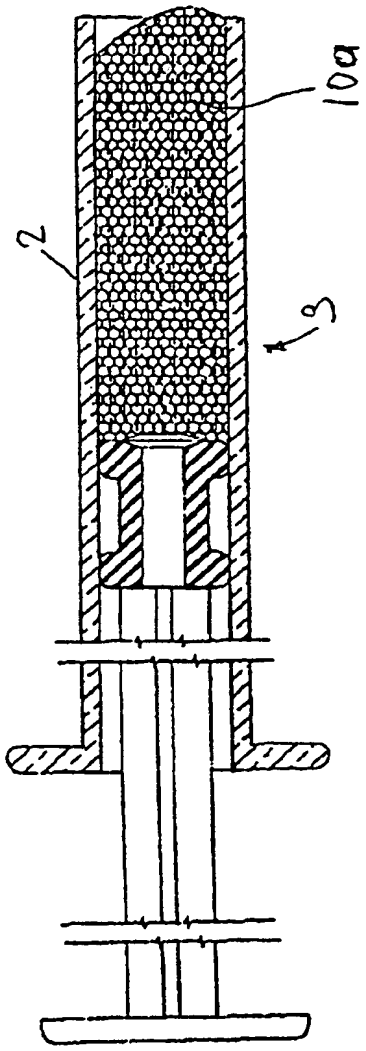


FIG. 5

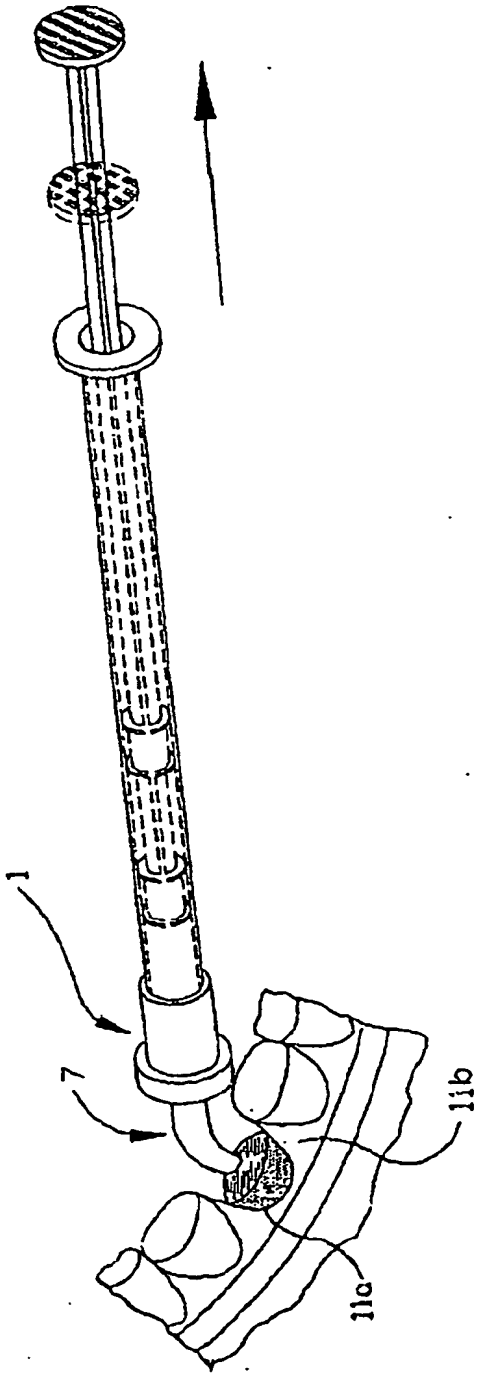
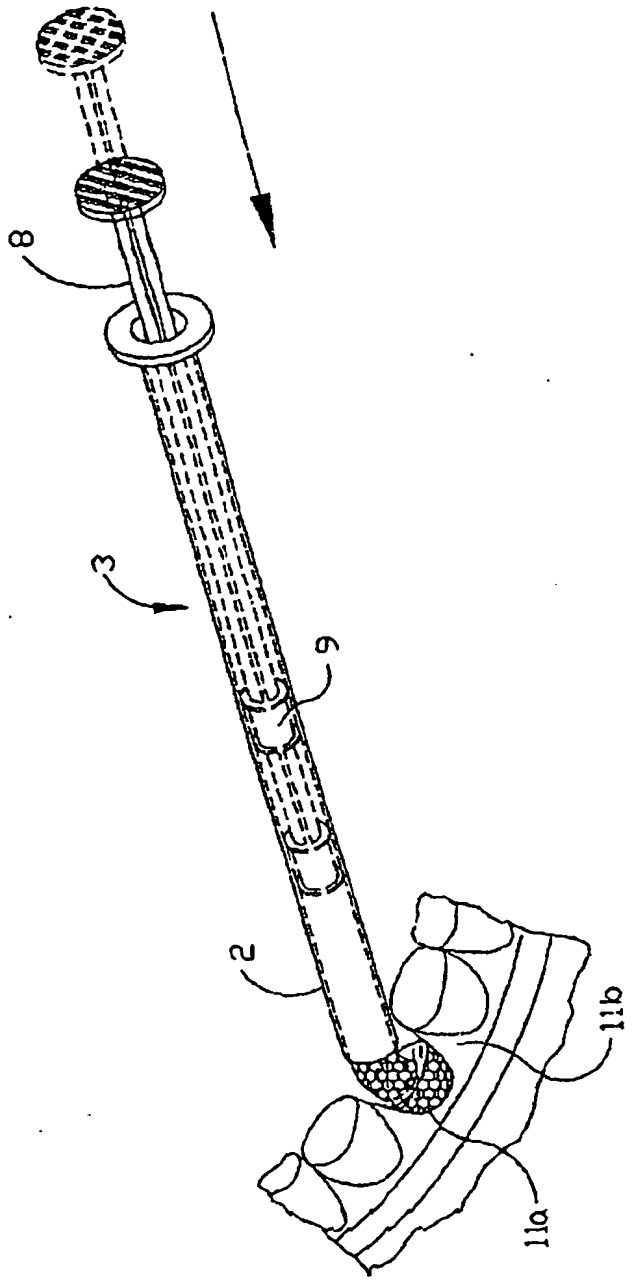


FIG. 6



European Patent Office

PARTIAL EUROPEAN SEARCH REPORT

which under Rule 45 of the European Patent Convention shall be considered, for the purposes of subsequent proceedings, as the European search report

Application Number EP 99 30 8320

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.7)
A	US 4 911 641 A (DETSCH STEVEN G) 27 March 1990 (1990-03-27) * column 4, line 64 - column 5, line 6 * * figure 8 * ---	1	A61C8/00 A61B10/00
A	US 5 824 087 A (ASPDEN RICHARD MALCOM ET AL) 20 October 1998 (1998-10-20) * column 2, line 35 - line 64 * ---	1	
A	US 5 330 357 A (KELLER DUANE C) 19 July 1994 (1994-07-19) * figure 10 * ---	1	
A	WO 98 16268 A (REY CHRISTIAN ;AIOLOVA MARIA (US); ETEX CORP (US); LEE DOSUK D (US) 23 April 1998 (1998-04-23) * page 15, line 22 - line 30 * * page 16, line 6 - line 9 * ---	1	
A	US 5 269 785 A (BONUTTI PETER M) 14 December 1993 (1993-12-14) * column 8, line 64 - column 9, line 35 * --- -/--	1	

TECHNICAL FIELDS SEARCHED (Int.Cl.7)

A61C
A61F
A61B

INCOMPLETE SEARCH

The Search Division considers that the present application, or one or more of its claims, does/do not comply with the EPC to such an extent that a meaningful search into the state of the art cannot be carried out, or can only be carried out partially, for these claims.

Claims searched completely :

1-4

Claims searched incompletely :

Claims not searched :

5-7

Reason for the limitation of the search:

Article 52 (4) EPC - Method for treatment of the human or animal body by surgery

Place of search	Date of completion of the search	Examiner
THE HAGUE	6 April 2000	Sedy, R

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
Y : particularly relevant if combined with another document of the same category
A : technological background
O : non-written disclosure
P : intermediate document

T : theory or principle underlying the invention
E : earlier patent document, but published on, or after the filing date
D : document cited in the application
L : document cited for other reasons

& : member of the same patent family, corresponding document

EPO FORM 1503 03.82 (P04C07)

European Patent Office

PARTIAL EUROPEAN SEARCH REPORT

Application Number
EP 99 30 8320

DOCUMENTS CONSIDERED TO BE RELEVANT			CLASSIFICATION OF THE APPLICATION (Int.Cl.7)
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	
A	US 4 366 822 A (ALTSHULER JOHN H) 4 January 1983 (1983-01-04) * abstract; figures *	1,4	
			TECHNICAL FIELDS SEARCHED (Int.Cl.7)

EPO FORM 1503 03.82 (P04C10)

ANNEX TO THE EUROPEAN SEARCH REPORT ON EUROPEAN PATENT APPLICATION NO. EP 99 30 8320

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report. The members are as contained in the European Patent Office EDP file on
The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

06-04-2000

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 4911641 A	27-03-1990	US 5073114 A	17-12-1991
US 5824087 A	20-10-1998	AU 2218395 A	30-10-1995
		DE 19581923 T	12-02-1998
		WO 9527518 A	19-10-1995
		GB 2301531 A,B	11-12-1996
		ZA 9502880 A	21-12-1995
US 5330357 A	19-07-1994	US 5129824 A	14-07-1992
		AU 6641990 A	24-07-1991
		CA 2071970 A,C	22-06-1991
		EP 0506679 A	07-10-1992
		JP 5502390 T	28-04-1993
		WO 9109574 A	11-07-1991
WO 9816268 A	23-04-1998	US 6027742 A	22-02-2000
		AU 4674697 A	11-05-1998
		EP 0936929 A	25-08-1999
US 5269785 A	14-12-1993	US 5403317 A	04-04-1995
		US 5577517 A	26-11-1996
		US 5694951 A	09-12-1997
		US 5935131 A	10-08-1999
US 4366822 A	04-01-1983	DE 3045245 A	19-06-1981
		JP 56080238 A	01-07-1981

For more details about this annex : see Official Journal of the European Patent Office, No. 12/82